

We claim:

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1. A texture masked particle comprising
 - a) a core containing an active ingredient;
 - b) a first coating layer comprised of a taste masking agent that substantially covers the core; and
 - c) a second coating layer on the surface of the first coating layer, the second coating layer comprised of
 - 10 i) a film forming polymer; and
 - ii) an anti-grit agent.

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2. The particle of claim 1, wherein the second coating layer substantially covers the first coating layer.

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3. The particle of claim 1, wherein the active ingredient is selected from the group consisting of a nonsteroidal anti-inflammatory drug, acetaminophen, pseudoephedrine, phenylpropanolamine, chlorpheniramine, dextromethorphan, diphenhydramine, dimenhydrinate, meclizine, famotidine, loperamide, ranitidine, cimetidine, astemizole, loratadine, desloratadine, fexofenadine, cetirizine, antacids, pharmaceutically acceptable salts thereof, metabolites thereof, and mixtures thereof.

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4. The particle of claim 1, wherein the taste masking agent is comprised of a mixture of a) an enteric polymer; and b) an insoluble film forming polymer.

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5. The particle of claim 4, wherein the enteric polymer is selected from the group consisting of hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, cellulose acetate phthalate, and mixtures thereof.

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6. The particle of claim 4, wherein the insoluble film forming polymer is selected from the group consisting of cellulose acetate, ethylcellulose, and mixtures thereof.

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7. The particle of claim 4, wherein the weight ratio of enteric polymer to insoluble film forming polymer in the first coating layer is in the range of about 20:80 to about 80:20.

8. The particle of claim 1 which meets the USP dissolution specification for immediate release dosage forms containing the particular active ingredient.

9. The particle of claim 1 wherein the film forming polymer is selected from the group consisting of hydroxypropyl methylcellulose, hydroxypropyl cellulose, hydroxyethyl cellulose, and

sodium carboxy methyl cellulose, starches, alginates, polyvinyl alcohols, xanthan gums, guar gums, polysaccharides, pectins, gelatins, and mixtures thereof.

5 10. The particle of claim 1 wherein the anti-grit agent is selected from the group consisting of polyethylene oxide, polyethylene glycol, and mixtures thereof.

11. The particle of claim 1 wherein the second coating layer is comprised of a mixture of hydroxypropyl methylcellulose and polyethylene glycol.

10 12. The particle of claim 1 wherein the weight ratio of film forming polymer to anti-grit agent in the second coating layer is in the range of about 10:90 to about 90:10.

13. The particle of claim 1 wherein the weight ratio of film forming polymer to anti-grit agent in the second coating layer is in the range of about 50:50.

15 14. A tablet comprised of the particles of claim 1.

15. A chewable tablet comprised of the particles of claim 1.

20 16. The chewable tablet of claim 15, wherein the first coating layer is substantially free of plasticizer.

25 17. The chewable tablet of claim 15, wherein the active ingredient is a nonsteroidal anti-inflammatory drug, acetaminophen, pseudoephedrine, phenylpropanolamine, chlorpheniramine, dextromethorphan, diphenhydramine, dimenhydrinate, meclizine, famotidine, loperamide, ranitidine, cimetidine, astemizole, loratadine, desloratadine, fexofenadine, cetirizine, antacids, pharmaceutically acceptable salts thereof, metabolites thereof, and mixtures thereof.

30 18. The chewable tablet of claim 15 which meets the USP dissolution specification for immediate release chewable tablets containing the particular active ingredient.

35 19. The chewable tablet of claim 15 wherein the film forming polymer is selected from the group consisting of hydroxypropyl methylcellulose, hydroxypropyl cellulose, hydroxyethyl cellulose, and sodium carboxy methyl cellulose, starches, alginates, polyvinyl alcohols, xanthan gums, guar gums, polysaccharides, pectins, gelatins, and mixtures thereof.

20. The chewable tablet of claim 15 wherein the anti-grit agent is selected from the group consisting of polyoxyethylene glycol, polyethylene glycol, and mixtures thereof.

21. The chewable tablet of claim 15 wherein the second coating layer is comprised of a mixture of hydroxypropyl methylcellulose and polyethylene glycol.

22. The chewable tablet of claim 15 wherein the weight ratio of film forming polymer to anti-grit agent in the second coating layer is in the range of about 10:90 to about 90:10.

23. A rapidly disintegrating tablet comprised of the particles of claim 1.

24. The rapidly disintegrating tablet of claim 23, wherein the first coating layer or the second coating layer is substantially free of plasticizer.

25. The rapidly disintegrating tablet of claim 23, wherein the active ingredient is a nonsteroidal anti-inflammatory drug, acetaminophen, pseudoephedrine, phenylpropanolamine, chlorpheniramine, dextromethorphan, diphenhydramine, dimenhydrinate, meclizine, famotidine, loperamide, ranitidine, cimetidine, astemizole, loratadine, desloratadine, fexofenadine, cetirizine, antacids, pharmaceutically acceptable salts thereof, metabolites thereof, and mixtures thereof.

26. The rapidly disintegrating tablet of claim 23 which meets the USP dissolution specification for immediate release chewable tablets containing the particular active ingredient.

27. The rapidly disintegrating tablet of claim 23 wherein the film forming polymer is selected from the group consisting of hydroxypropyl methylcellulose, hydroxypropyl cellulose, hydroxyethyl cellulose, and sodium carboxy methyl cellulose, starches, alginates, polyvinyl alcohols, xanthan gums, guar gums, polysaccharides, pectins, gelatins, and mixtures thereof.

28. The rapidly disintegrating tablet of claim 23 wherein the anti-grit agent is selected from the group consisting of polyoxyethylene glycol, polyethylene glycol, and mixtures thereof.

29. The rapidly disintegrating tablet of claim 23 wherein the second coating layer is comprised of a mixture of hydroxypropyl methylcellulose and polyethylene glycol.

30. The rapidly disintegrating tablet of claim 23 wherein the weight ratio of film forming polymer to anti-grit agent in the second coating layer is in the range of about 10:90 to about 90:10.

31. A method of texture masking particles comprising an active ingredient, which comprises:

a) applying a substantially continuous first coating layer over the particles, the first coating layer comprising a taste masking agent; and

b) applying a second coating layer on the surface of the first coating layer, the second coating layer comprising a mixture of 1) a film forming polymer; and 2) an anti-grit agent.



32. The method of claim 31, wherein the active ingredient is a nonsteroidal anti-inflammatory drug, acetaminophen, pseudoephedrine, phenylpropanolamine, chlorpheniramine, dextromethorphan, diphenhydramine, dimenhydrinate, meclizine, famotidine, loperamide,
5 ranitidine, cimetidine, astemizole, loratadine, desloratadine, fexofenadine, cetirizine, antacids, pharmaceutically acceptable salts thereof, metabolites thereof, and mixtures thereof.

33. The method of claim 31 wherein the film forming polymer is selected from the group consisting of hydroxypropyl methylcellulose, hydroxypropyl cellulose, hydroxyethyl cellulose,
10 and sodium carboxy methyl cellulose, starches, alginates, polyvinyl alcohols, xanthan gums, guar gums, polysaccharides, pectins, gelatins, and mixtures thereof.

34. The method of claim 31 wherein the anti-grit agent is selected from the group consisting of polyoxyethylene, polyethylene glycol, and mixtures thereof.

35. The method of claim 31 wherein the second coating layer is comprised of a mixture of hydroxypropyl methylcellulose and polyethylene glycol.

36. The method of claim 31 wherein the weight ratio of film forming polymer to anti-grit agent in the second coating layer is in the range of about 10:90 to about 90:10.

37. A texture masked particle comprising:
a) a core containing an active ingredient; and
b) a texture masking coating layer on the surface of the core, the texture masking coating
25 layer comprised of
i) a film forming polymer; and
ii) an anti-grit agent.

38. The particle of claim 37, wherein the active ingredient is a nonsteroidal anti-inflammatory drug, acetaminophen, pseudoephedrine, phenylpropanolamine, chlorpheniramine, dextromethorphan, diphenhydramine, dimenhydrinate, meclizine, famotidine, loperamide,
30 ranitidine, cimetidine, astemizole, loratadine, desloratadine, fexofenadine, cetirizine, antacids, pharmaceutically acceptable salts thereof, metabolites thereof, and mixtures thereof.

39. The particle of claim 37 which meets the USP dissolution specification for immediate release dosage forms containing the particular active ingredient.

40. The particle of claim 37 wherein the film forming polymer is selected from the group consisting of hydroxypropyl methylcellulose, hydroxypropyl cellulose, hydroxyethyl cellulose, and

sodium carboxy methyl cellulose, starches, alginates, polyvinyl alcohols, xanthan gums, guar gums, polysaccharides, pectins, gelatins, and mixtures thereof.

41. The particle of claim 37 wherein the anti-grit agent is selected from the group
5 consisting of polyethylene oxide, polyethylene glycol, and mixtures thereof.

42. The particle of claim 37 wherein the texture masking coating layer is comprised of a mixture of hydroxypropyl methylcellulose and polyethylene glycol.

10 43. The particle of claim 37 wherein the weight ratio of film forming polymer to anti-grit agent in the texture masking coating layer is in the range of about 10:90 to about 90:10.

44. The particle of claim 37 wherein the weight ratio of film forming polymer to anti-grit agent in the texture masking coating layer is in the range of about 50:50.

15 45. A tablet comprised of the particles of claim 37.

46. A chewable tablet comprised of the particles of claim 37.

20 47. The chewable tablet of claim 46, wherein the active ingredient is a nonsteroidal anti-inflammatory drug, acetaminophen, pseudoephedrine, phenylpropanolamine, chlorpheniramine, dextromethorphan, diphenhydramine, dimenhydrinate, meclizine, famotidine, loperamide, ranitidine, cimetidine, astemizole, loratadine, desloratadine, fexofenadine, cetirizine, antacids, pharmaceutically acceptable salts thereof, metabolites thereof, and mixtures thereof.

25 48. The chewable tablet of claim 46 wherein the film forming polymer is selected from the group consisting of hydroxypropyl methylcellulose, hydroxypropyl cellulose, hydroxyethyl cellulose, and sodium carboxy methyl cellulose, starches, alginates, polyvinyl alcohols, xanthan gums, guar
30 gums, polysaccharides, pectins, gelatins, and mixtures thereof.

49. The chewable tablet of claim 46 wherein the anti-grit agent is selected from the group consisting of polyoxyethylene glycol, polyethylene glycol, and mixtures thereof.

35 50. The chewable tablet of claim 46 wherein the texture-masking coating layer is comprised of a mixture of hydroxypropyl methylcellulose and polyethylene glycol.

51. The chewable tablet of claim 46 wherein the weight ratio of film forming polymer to anti-grit agent in the texture-masking coating layer is in the range of about 10:90 to about 90:10.

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52. A rapidly disintegrating tablet comprised of the particles of claim 37.

53. The rapidly disintegrating tablet of claim 52, wherein the active ingredient is a nonsteroidal anti-inflammatory drug, acetaminophen, pseudoephedrine, phenylpropanolamine, chlorpheniramine, dextromethorphan, diphenhydramine, dimenhydrinate, meclizine, famotidine, loperamide, ranitidine, cimetidine, astemizole, loratadine, desloratadine, fexofenadine, cetirizine, antacids, pharmaceutically acceptable salts thereof, metabolites thereof, and mixtures thereof.

54. The rapidly disintegrating tablet of claim 52 wherein the film forming polymer is selected from the group consisting of hydroxypropyl methylcellulose, hydroxypropyl cellulose, hydroxyethyl cellulose, and sodium carboxy methyl cellulose, starches, alginates, polyvinyl alcohols, xanthan gums, guar gums, polysaccharides, pectins, gelatins, and mixtures thereof.

55. The rapidly disintegrating tablet of claim 52 wherein the anti-grit agent is selected from the group consisting of polyoxyethylene glycol, polyethylene glycol, and mixtures thereof.

56. The rapidly disintegrating tablet of claim 52 wherein the texture masking coating layer is comprised of a mixture of hydroxypropyl methylcellulose and polyethylene glycol.

57. The rapidly disintegrating tablet of claim 52 wherein the weight ratio of film forming polymer to anti-grit agent in the texture masking coating layer is in the range of about 10:90 to about 90:10.

58. A method of texture masking particles comprising an active ingredient, which comprises:

a) applying a coating layer over the active ingredient, the coating layer comprising a mixture of 1) a film forming polymer; and 2) an anti-grit agent.

59. The method of claim 58, wherein the active ingredient is a nonsteroidal anti-inflammatory drug, acetaminophen, pseudoephedrine, phenylpropanolamine, chlorpheniramine, dextromethorphan, diphenhydramine, dimenhydrinate, meclizine, famotidine, loperamide, ranitidine, cimetidine, astemizole, loratadine, desloratadine, fexofenadine, cetirizine, antacids, pharmaceutically acceptable salts thereof, metabolites thereof, and mixtures thereof.

60. The method of claim 58 wherein the film forming polymer is selected from the group consisting of hydroxypropyl methylcellulose, hydroxypropyl cellulose, hydroxyethyl cellulose, and sodium carboxy methyl cellulose, starches, alginates, polyvinyl alcohols, xanthan gums, guar gums, polysaccharides, pectins, gelatins, and mixtures thereof.

61. The method of claim 58 wherein the anti-grit agent is selected from the group consisting of polyoxyethylene glycol, polyethylene glycol, and mixtures thereof.

5 62. The method of claim 58 wherein the coating layer is comprised of a mixture of hydroxypropyl methylcellulose and polyethylene glycol.

63. The method of claim 58 wherein the weight ratio of film forming polymer to anti-grit agent in the texture masking coating layer is in the range of about 10:90 to about 90:10.

10 64. The particle of claim 37 wherein the texture masking coating layer substantially covers the core.

65. A tablet comprising the particles of claim 64.

15 66. The method of claim 58 wherein the coating layer is substantially continuous.

67. A texture masked particle comprising a matrix, the matrix is comprised of:

- a) an active ingredient;
- b) a film forming polymer; and
- 20 c) an anti-grit agent,

wherein the film forming polymer and anti-grit agent are exposed at the surface of the particle in an amount effective for texture masking the active ingredient.


25 68. The particle of claim 67 wherein the average diameter of said particle is from about 50 to about 500 microns.

69. The particle of claim 67 wherein the weight ratio of film-forming polymer to anti-grit agent is from about 10:90 to about 90:10.

30 70. The particle of claim 67 wherein the film forming polymer and the anti-grit agent together are present in an amount, based on the weight of the texture masked particle, from about 25 to about 90%

35 71. The particle of claim 67 which is made by spray-drying a mixture comprising the active ingredient, a film forming polymer; and an anti-grit agent.

72. A method for making texture masked particles comprising an active ingredient, the method comprising spray-drying a mixture comprising

- 
- a) a film forming polymer and an anti-grit agent, which together are present in an amount effective for texture masking the active ingredient; and
- b) the active ingredient.

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